CLAIMS

What is claimed is:

1. A method of eliciting an immune response against an antigen in a vertebrate subject, the method comprising the steps of:

(a) providing an antigen-adjuvant composition comprising the antigen and an adjuvant molecule having biological activity in mucosal tissues and having less toxicity and less immunogenicity than cholera toxin; and

(b) administering said antigen-adjuvant composition to the vertebrate subject in a manner such that initial contact occurs in mucosal tissue of the vertebrate subject, whereby an immune response is elicited.

2. The method of claim 1, wherein the antigen-adjuvant composition further comprises a pharmaceutically acceptable vehicle and the antigen-adjuvant composition is carried therein.

3. The method of claim 2, wherein the pharmaceutically acceptable vehicle is selected from the group consisting of distilled water and phosphate-buffered saline.

4. The method of claim 1, wherein the antigen-adjuvant composition is free of mineral adjuvants, preservatives or stabilizers, and wherein the antigen and adjuvant are not conjugated together.

5. The method of claim 1, wherein the adjuvant is selected from the group consisting of cytokines, chemokines, growth factors, angiogenic factors, apoptosis inhibitors, hormones, and combinations thereof.

6. The method of claim 5, wherein the cytokine is selected from the group consisting of an IL, TGFβ, GM-CSF, IFNα, and combinations thereof.

7. The method of claim 6, wherein the IL is selected from the group consisting of IL-1, IL-1α, IL-1β, IL-2, IL-5, IL-6, IL-12, IL-15, IL-18 and combinations thereof.

8. The method of claim 7, wherein the IL comprises IL-1α or IL-1β and the IL-1α or IL-1β adjuvant is present in the antigen-adjuvant composition in an amount ranging from about 10 to about 1000 micrograms per kilogram body weight of the vertebrate subject.

9. The method of claim 8, wherein the IL-1α or IL-1β adjuvant is present in the antigen-adjuvant composition in an amount ranging from about 50 to about 500 micrograms per kilogram body weight of the vertebrate subject.

10. The method of claim 9, wherein the IL-1α or IL-1β adjuvant is present in the antigen-adjuvant composition in an amount ranging from about 60 to about 200 micrograms per kilogram body weight of the vertebrate subject.

11. The method of claim 7, wherein the IL comprises recombinant IL-1β and is present in the antigen-adjuvant composition in an amount ranging from about 1 to about 100 milligrams per kilogram body weight of the vertebrate subject.

12. The method of claim 11, wherein the recombinant IL-1β is present in the antigen-adjuvant composition in an amount ranging from about 5 to about 50 milligrams per kilogram body weight of the vertebrate subject.

13. The method of claim 12, wherein the recombinant IL-1β is present in the antigen-adjuvant composition in an amount of about 10 to about 20 milligrams per kilogram body weight of the vertebrate subject.

14. The method of claim 5, wherein the chemokine is selected from the group consisting of LARC, PARC, MDC, TARC, SLC, FKN, and combinations thereof.

15. The method of claim 5, wherein the apoptosis inhibitor is selected from the group consisting of toso, inhibitors of caspase-8, and combinations thereof.

16. The method of claim 5, wherein the angiogenic factor is selected from the group consisting of a basic fibroblast growth factor, a vascular endothelial growth factor, a hyaluronan fragment, and combinations thereof.

17. The method of claim 1, wherein said manner of administration is selected from the group consisting of intranasal administration, intravaginal administration, and intrarectal administration.

18. The method of claim 1, wherein the antigen-adjuvant composition is administered once a week over a period of one to three weeks.

19. The method of claim 1, wherein the antigen-adjuvant composition is administered once every two weeks over a period of two to six weeks.

20. The method of claim 1, wherein the antigen-adjuvant composition is administered once during a first week, and the method further comprises the step of administering the antigen only once a week over a period of one to two weeks following the first week.

21. The method of claim 1, wherein the antigen-adjuvant composition is administered once during a first biweekly period, and the method further comprises the step of administering the antigen only once every two weeks over a period of two to four weeks following the first biweekly period.

22. The method of claim 1, wherein the immune response comprises a systemic immune response.

23. The method of claim 22, wherein the systemic immune response comprises the production of antigen-specific IgG's at a titer of at least about 1:10,000.

24. The method of claim 23, wherein the systemic immune response comprises the production of antigen-specific IgG's at a titer of at least about 1:20,000.

25. The method of claim 1, wherein the immune response comprises a mucosal immune response.

26. The method of claim 25, wherein the mucosal immune response comprises production of antigen-specific IgA's in mucosal tissue at a site in the vertebrate subject removed from the site of administration.

27. The method of claim 26, wherein the antigen-specific IgA's are produced at a titer of at least about 1:100.

28. The method of claim 27, wherein the antigen-specific IgA's are produced at a titer of at least about 1:500.

29. The method of claim 1, wherein the immune response comprises a cell-mediated immune response.

30. The method of claim 29, wherein the cell-mediated immune response comprises proliferation of lymphocytes.

31. The method of claim 30, wherein the proliferation of lymphocytes is further characterized by at least about a ten (10)-fold increase in lymphocytes as compared to an unimmunized state.

32. The method of claim 31, wherein the proliferation of lymphocytes is further characterized by at least about a fifty (50)-fold increase in lymphocytes as compared to an unimmunized state.

33. The method of claim 1, wherein the vertebrate subject is a mammal.

34. The method of claim 33, wherein the mammal is a human.

35. A method of eliciting an immune response against an antigen in a vertebrate subject, the method comprising the steps of:

(a) providing an antigen-adjuvant composition comprising the antigen and a cytokine adjuvant molecule having biological activity in mucosal tissues, wherein the antigen-adjuvant composition is free of alum and wherein the antigen and adjuvant are not conjugated together; and

(b) administering said antigen-adjuvant composition to the vertebrate subject in a manner such that initial contact occurs in mucosal tissue of the vertebrate subject, whereby an immune response is elicited.

36. The method of claim 35, wherein the antigen-adjuvant composition further comprises a pharmaceutically acceptable vehicle and the antigen-adjuvant composition is carried therein.

37. The method of claim 36, wherein the pharmaceutically acceptable vehicle is selected from the group consisting of distilled water and phosphate-buffered saline.

38. The method of claim 35, wherein the cytokine is selected from the group consisting of an IL, TGFβ, GM-CSF, IFNα, and combinations thereof.

39. The method of claim 38, wherein the IL is selected from the group consisting of IL-1, IL-1α, IL-1β, IL-2, IL-5, IL-6, IL-12, IL-15, IL-18 and combinations thereof.

40. The method of claim 39, wherein the IL comprises IL-1α or IL-1β and the IL-1α or IL-1β adjuvant is present in the antigen-adjuvant composition in an amount ranging from about 10 to about 1000 micrograms per kilogram body weight of the vertebrate subject.

41. The method of claim 40, wherein the IL-1α or IL-1β adjuvant is present in the antigen-adjuvant composition in an amount ranging from about 50 to about 500 micrograms per kilogram body weight of the vertebrate subject.

42. The method of claim 41, wherein the IL-1α or IL-1β adjuvant is present in the antigen-adjuvant composition in an amount ranging from about 60 to about 200 micrograms per kilogram body weight of the vertebrate subject.

43. The method of claim 39, wherein the IL comprises recombinant IL-1β and is present in the antigen-adjuvant composition in an amount ranging from about 1 to about 100 milligrams per kilogram body weight of the vertebrate subject.

44. The method of claim 43, wherein the recombinant IL-1β is present in the antigen-adjuvant composition in an amount ranging from about 5 to about 50 milligrams per kilogram body weight of the vertebrate subject.

45. The method of claim 44, wherein the recombinant IL-1β is present in the antigen-adjuvant composition in an amount of about 10 to about 20 milligrams per kilogram body weight of the vertebrate subject.

46. The method of claim 35, wherein said manner of administration is selected from the group consisting of intranasal administration, intravaginal administration, and intrarectal administration.

47. The method of claim 35, wherein the antigen-adjuvant composition is administered once a week over a period of one to three weeks.

48. The method of claim 35, wherein the antigen-adjuvant composition is administered once every two weeks over a period of two to six weeks.

49. The method of claim 35, wherein the antigen-adjuvant composition is administered once during a first week, and the method further

comprises the step of administering the antigen only once a week over a period of one to two weeks following the first week.

50. The method of claim 35, wherein the antigen-adjuvant composition is administered once during a first biweekly period, and the method further comprises the step of administering the antigen only once every two weeks over a period of two to four weeks following the first biweekly period.

51. The method of claim 35, wherein the immune response comprises a systemic immune response.

52. The method of claim 51, wherein the systemic immune response comprises the production of antigen-specific IgG's at a titer of at least about 1:10,000.

53. The method of claim 52, wherein the systemic immune response comprises the production of antigen-specific IgG's at a titer of at least about 1:20,000.

54. The method of claim 35, wherein the immune response comprises a mucosal immune response.

55. The method of claim 54, wherein the mucosal immune response comprises production of antigen-specific IgA's in mucosal tissue at a site in the vertebrate subject removed from the site of administration.

56. The method of claim 55, wherein the antigen-specific IgA's are produced at a titer of at least about 1:100.

57. The method of claim 56, wherein the antigen-specific IgA's are produced at a titer of at least about 1:500.

58. The method of claim 35, wherein the immune response comprises a cell-mediated immune response.

59. The method of claim 36, wherein the cell-mediated immune response comprises proliferation of lymphocytes.

60. The method of claim 59, wherein the proliferation of lymphocytes is further characterized by at least about a ten (10)-fold increase in lymphocytes as compared to an unimmunized state.

61. The method of claim 60, wherein the proliferation of lymphocytes is further characterized by at least about a fifty (50)-fold increase in lymphocytes as compared to an unimmunized state.

62. The method of claim 35, wherein the vertebrate subject is a mammal.

63. The method of claim 62, wherein the mammal is a human.